

Scientific Title	A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Itacitinib or Placebo in Combination With Corticosteroids for the Treatment of First-Line Acute Graft Versus-Host Disease
Short Title	Gravitas-301 (MEDPACE)
Id KN/ELN	LN_NN_2018_657
Trialgoup	NN
Type of Trial	multicentric, randomized, placebo-kontrolliert, double-blind, double-group
Phase	Phase III
Disease	Acute lymphoblastic leukemia(ALL) Stem cell transplantation
Stage of Disease	.
Inclusion Criteria	<ul style="list-style-type: none">- Male or female, 18 years of age or older.- Has undergone 1 allo-HSCT from any donor (related or unrelated with any degree of HLA matching) and any donor source (bone marrow, peripheral blood stem cells, or cord blood) for a hematologic malignancy or disorder. Recipients of myeloablative and reduced-intensity conditioning regimens are eligible.- Clinically suspected Grade II to IV aGVHD as per MAGIC criteria, occurring after allo-HSCT and any GVHD prophylaxis regimen. Biopsies should be obtained to pathologically confirm aGVHD; in cases where a biopsy is negative, is unable to be obtained, or is clinically contraindicated, clinical suspicion of aGVHD by the treating physician is sufficient, provided that alternative diagnoses of drug effects or infection are adequately ruled out- Evidence of myeloid engraftment (eg, absolute neutrophil count $\geq 0.5 \times 10^9/L$ for 3 consecutive assessments if ablative therapy was previously used). Use of growth factor supplementation is allowed.
Exclusion Criteria	<ul style="list-style-type: none">- Has received more than 1 allo-HSCT.- Has received more than 2 days of systemic corticosteroids for acute-GVHD.- Presence of GVHD overlap syndrome.- Presence of an active uncontrolled infection.
Age	≥ 18 years
Status	Active
start of Recruitment	01.02.2018
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Sponsors	Incyte Corporation
Other Registers	European Clinical Trials Database - EUDRACT2017-000538-78